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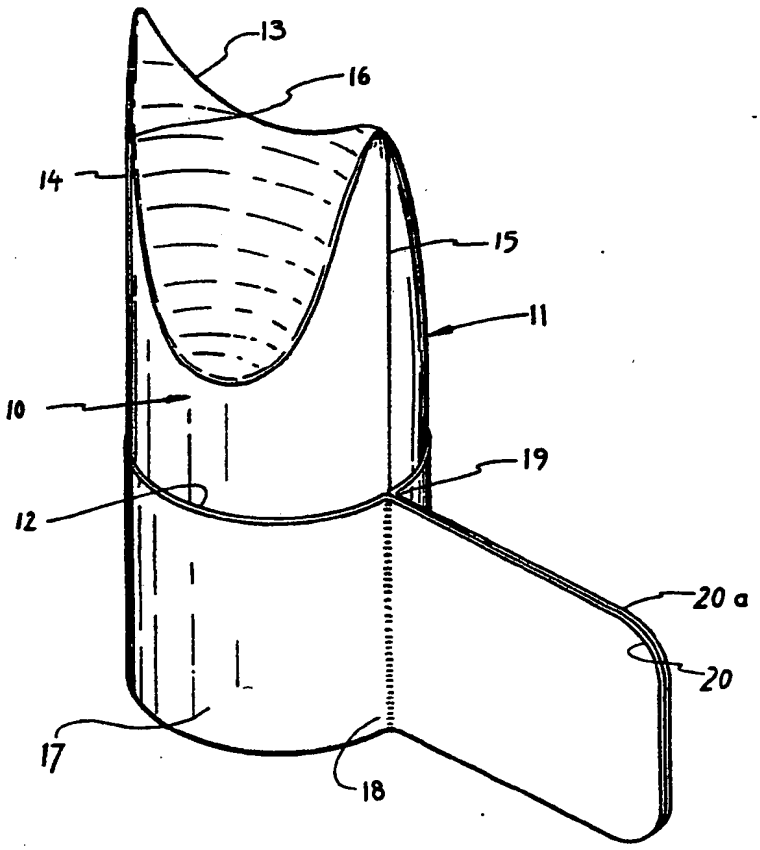
(54) Title: PROSTHETIC VENOUS VALVE

(57) Abstract

A prosthetic venous valve has two cusp-forming portions (10, 11) and a base portion (17). Each cusp-forming portion (10, 11) has an arcuate boundary (16) of elliptical shape that ends from the top (13) of the cusp-forming portion (10, 11) towards the base portion (17). The valve is positioned around a vein and the tabs (20, 20a) are secured together so that the valve forms a tube around the vein. A portion of the vein wall is then intussuscepted over the cusp-forming portion to form a venous valve in which blood does not come in contact with the cusp-forming portions (10, 11).



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PROSTHETIC VENOUS VALVE

FIELD OF INVENTION

This invention relates to an implantable prosthetic venous valve that may be used to restore competence to a venous system.

BACKGROUND ART

As is well known, the function of the venous system is to direct the flow of blood towards the heart and to this end the venous system contains natural valves which prevent back-flow of blood. A number of factors can lead to the incompetence of such valves and various attempts have been made to restore competency to incompetent venous valves using surgical restoration techniques such as venous valve transplants, venous transposition and venous valvuloplasty.

In some circumstances, incompetent venous valves can be restored by placing a band of biocompatible material around the valve at the site of the valve in the form of a cuff and then reducing the circumference of the cuff (and hence the diameter of the vein at the valve site) until competency of the valve is restored. However, there are cases where neither the surgical restoration techniques nor the cuff technique are applicable and there is, therefore, a need for a prosthetic venous valve.

An intussusception technique for creating venous valves from a length of vein is described in AN OPERATIVE TECHNIQUE FOR THE CONSTRUCTION OF VENOUS VALVES by B. Eiseman and W. Malette Surg. Gyn. Obst. 1953, 97: 731-734. This method

simply involved the intussusception of the vein wall and made no use of any implantable device. In essence, the intussusception method uses a portion of the vein wall to form the cusps of the valve, but this approach does not take account for the fact the tensile strength of a normal valve cusp is at least three times that of a vein wall - see, for example, A STUDY OF THE MECHANICAL PROPERTIES OF FRESH AND PRESERVED HUMAN FEMORAL VEIN WALL AND VEIN CUSPS by Ackroyd J.S et al Br. J. Surg. 1985, 72: 117-119.

Prosthetic venous valves of bicuspid design which mimicked natural valve anatomy were disclosed in DEVELOPMENT OF A PROSTHETIC VENOUS VALVE by Hill R. et al Journal of Biomedical Materials Research, 1985, 19, 827-832. A stainless steel cylinder was first implanted into the vein as a support and the prosthetic valve was pulled over the support and secured in place by a ligature.

DISCLOSURE OF THE INVENTION

It is an object of this invention to provide a prosthetic venous valve which is located externally of the vein and placed into position by intussusception of the vein wall.

According to the invention there is provided an implantable prosthetic valve adapted to be placed into position by intussusception of a vein wall, said valve comprising an elongated cusp-forming portion and a base portion, said cusp-forming portion having an arcuate boundary adapted to form a portion of the intussuscepted vein wall

into a valve cusps.

Preferably, the arcuate boundary is of generally semi-elliptical form. In one form of the invention, the base portion has securing tabs at each extremity.

BRIEF DESCRIPTION OF THE DRAWINGS

In order that the invention may be more readily understood and put into practical effect, reference will now be made to the accompanying drawings in which:-

Fig. 1 is a perspective view of a prosthetic venous according to one embodiment of the invention

Fig. 2 is a perspective view of the valve of Fig. 1 being placed around a vein,

Fig. 3 is a view similar to Fig. 2 with the valve closed around the vein,

Fig. 4 is a view similar to Fig. 3 showing the commencement of intussusception of the vein over the valve,

Fig. 5 is a view similar to Fig. 4 showing the valve fully in place, intussusception complete and the cusps closed to prevent retrograde flow of blood,

Fig. 6 is a view similar to Fig. 5 with the cusps open to allow prograde or normal flow of blood,

Fig. 7 is a diagrammatic cross-sectional view of the valve shown in Fig. 5,

Fig. 8 is a view taken along lines 8-8 of Fig. 7 with the valve closed,

Fig. 9 is a diagrammatic cross-sectional view showing prograde or normal blood flow, and,

Fig. 10 is a view similar to Fig. 9 showing cusps closed to prevent retrograde flow of blood.

The prosthetic venous valve shown in the drawings is formed from flexible, implantable material such as poly silicone rubber by dip or injection moulding. The valve consists of a pair of cusp forming portions 10 and 11. The cusp-forming portion 10 has a bottom edge 12, top edge 13, opposed side edges 14, 15 and an arcuate boundary 16 adapted to form a cusp from the intussuscepted vein wall. As can be seen in Fig. 1, the material within the boundary 16 is concave to the remainder of the generally cylindrical form of the valve.

The cusp forming portion 11 is the mirror image of cusp-forming portion 10 with the two being integral with one another along edges 14 and being separated along edges 15. Beneath the cusp-forming portions 10, 11 there is a base portion 17 the extremities 18, 19 of which have securing tabs 20, 20a that extend outwardly from the generally cylindrical form of the valve as shown in Fig. 1.

The valve device is encircled around a vein 21 to be treated (see Fig. 2) and the tabs 20 and 20a are connected in any convenient way so that the base portion 17 forms a cuff around the vein (see Fig. 3).

A section 22 of the vein 21 is then intussuscepted over the cusp-forming portions 10 and 11 in the direction of

arrows A so that the cusp-forming portions 10, 11 are surrounded by overlapping portions 23, 24 of the section 22 of the vein 21. The technique of intussusception ensures that the blood only contacts vein endothelium and not the valve material. The valve is then secured in place by sutures 26. The cusps formed by the portions 10, 11 are normally directed towards one another and are so shaped that the mating portions 27, 28 of the intussuscepted vein wall form a linear closure at the vessel midline as shown in Fig. 8.

The valve cusps formed by portions 10, 11 are designed to close under the force of retrograde flowing blood as shown in Figs 5 and 10 and open during prograde or normal blood flow as shown in Figs. 6 and 9. Retrograde flow of blood forces the valve cusps together causing a fluid tight seal.

Should there be thickening of the venous wall at the location of the valve, the adventitia and part of the media is stripped off the vein in order to decrease the inertia of the cusp or apex portions of the valve members.

Competence of the implanted valve device can be assessed with an operative doppler technique or by occluding the vein distally and placing another digit proximally to force blood in a retro-grade direction towards the artificial valve. If the artificial valve is competent, the vein immediately proximal to the valve becomes distended and the vein immediately distal to the valve remains collapsed.

For example, the base portion of the valve may be made

of the same material as the remainder of the valve, and a separate cuff applied around the base portion 17 to provide a firmer base. Futhermore, the top edge 13 of each cusp-forming portion may be concavely curved to assist closure of the cusps. The valve may be a one piece moulding or made from separate cusp-forming portions and a separate base. One or more cusp-forming portions may be provided and, in some instances, the material within the boundary 16 may be omitted.

EXAMPLE

The technique of intussuscepting vein over a prosthetic valve has been carried out eight times in the internal jugular vein in sheep. The mean implant time was three weeks. In no case was there any evidence of thrombosis. There was in the early cases problems with adhesion of the vein wall to the cusp.

The valve illustrated in Fig. 1 has been implanted four times with resulting complete or near complete competence. Three of these have been harvested at a mean of one week. Two had no adhesions and one of these had complete competence. These two valves had a firmer cuff or base portion 17 which prevented surrounding tissues from pushing the vein wall 21 into contact with the cusps (i.e. vein portion 23).

Another example of the valve may be to create a one cusp valve or a valve with three or more cusps.

Various modifications may be made in details of design and constructions without departing from the scope and abmit of the invention.

CLAIMS

1. An implantable prosthetic valve adapted to be placed into position by intussusception of a vein wall, said valve comprising an elongated cusp-forming portion and a base portion, said cusp-forming portion having an arcuate boundary adapted to form a portion of the intussuscepted vein wall into a valve cusp.

2. A valve according to claim 1 wherein said cusp-forming portion is a first cusp-forming portion and further including a second cusp-forming portion also having an arcuate boundary adapted to form another portion of the intussuscepted vein wall into a second valve cusp.

3. A valve according to claim 2 wherein two cusp-forming portions are joined together along adjacent side boundaries.

4. A valve according to claim 3 wherein the cusp-forming portions and the base portions are of cylindrical form with the other side boundaries of the cusp-forming portions and the adjacent parts of the base portion being separated so that the cylindrical valve may be placed around the vein.

5. A valve according to any one of the preceding claims wherein the or each cusp-forming portion is of half-cylindrical form and the arcuate boundary extends from the edges of the end of the cusp-forming portion remote from the base portion towards but not to the base portion.

6. A valve according to any one of the preceding claims

wherein the arcuate boundary is of semi-elliptical form.

7. A valve according to any one of the preceding claims wherein the end of the or each cusp-forming portion remote from the base portion is straight.

8. A valve according to any one of the preceding claims wherein that part of the or each cusp-forming portion within the arcuate boundary and the end of the cusp-forming portion remote from the base portion is directed inwardly from the remainder of the cusp-forming portion.

9. A valve according to any one of the preceding claims wherein the valve is made from sheet-like implantable material.

10. A valve according to any one of the preceding claims wherein the base portion is of thicker material than the or each cusp-forming portion.

11. A valve according to any one of the preceding claims wherein the base portion includes extension portions that extend transversely of the valve.

12. A method of forming an artificial valve comprising the steps of:

i) placing a valve according to any one of claims 1 to 11 around a vein,

ii) closing the valve and securing the ends of the base portion,

iii) intussuscepting a portion of the vein wall over the cusp-forming portions of the valve, and,

iv) fixing the intussuscepted vein portion in position.

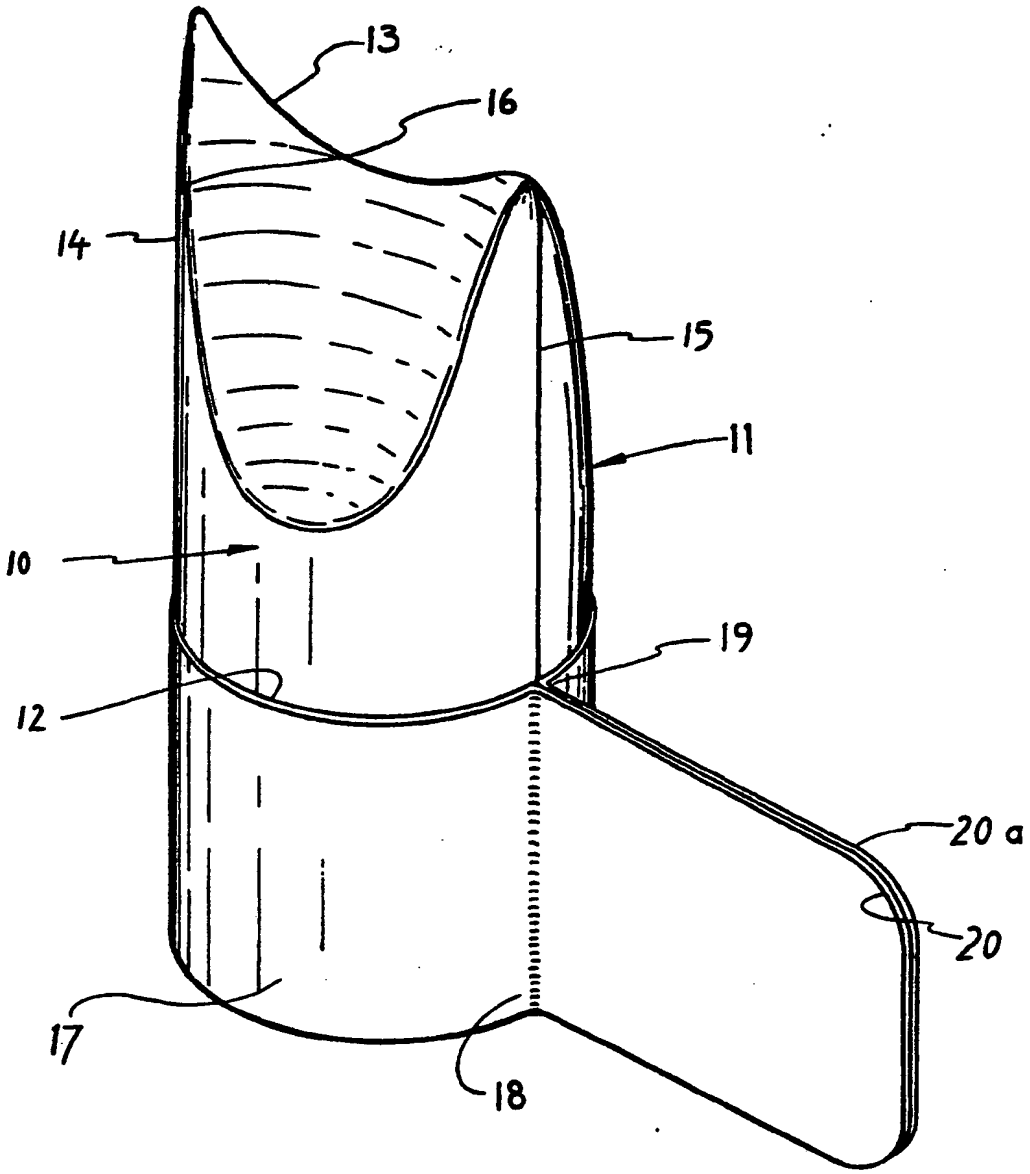

FIG. 1

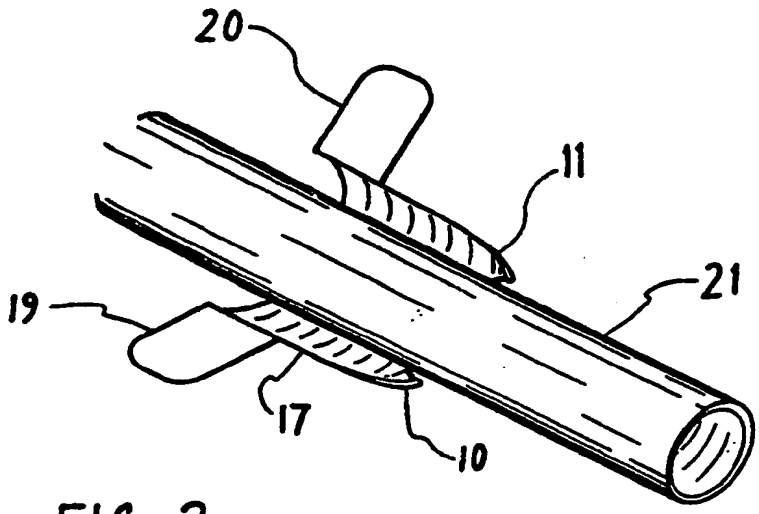

FIG. 2

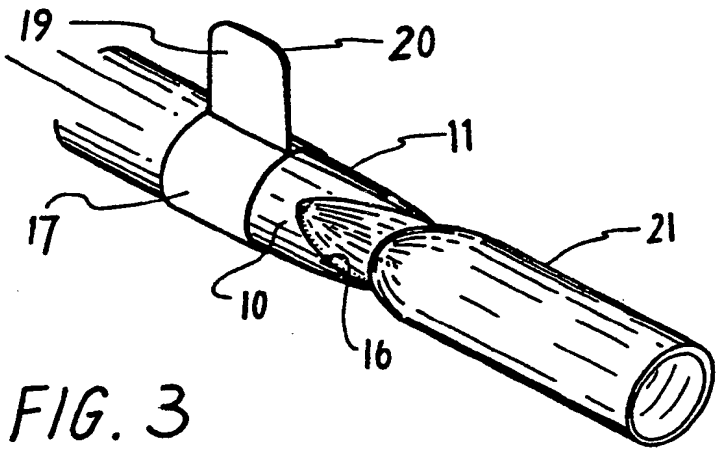

FIG. 3

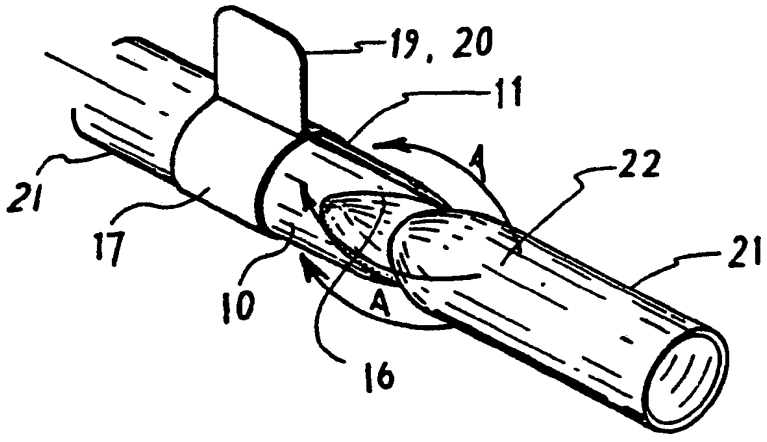

FIG. 4

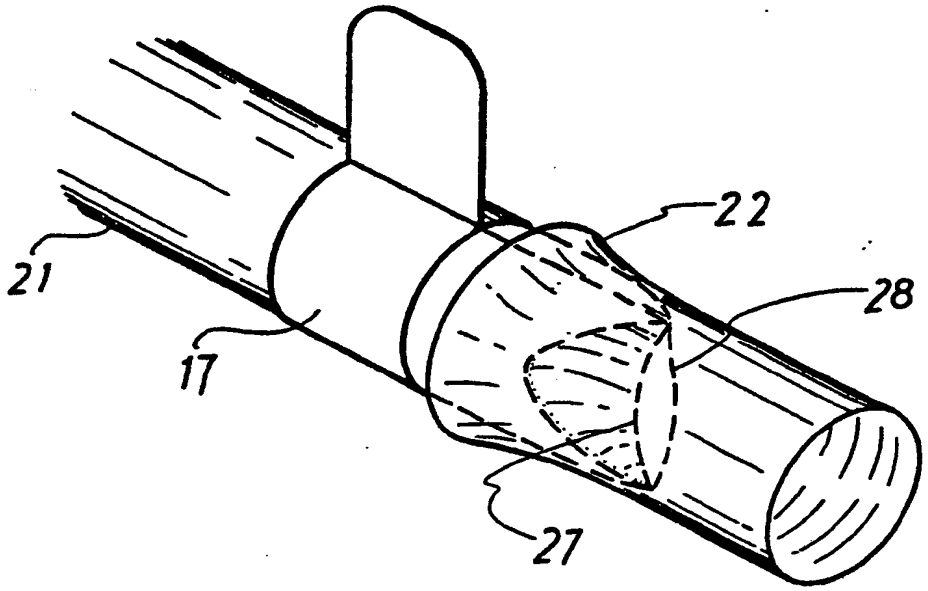

FIG. 6

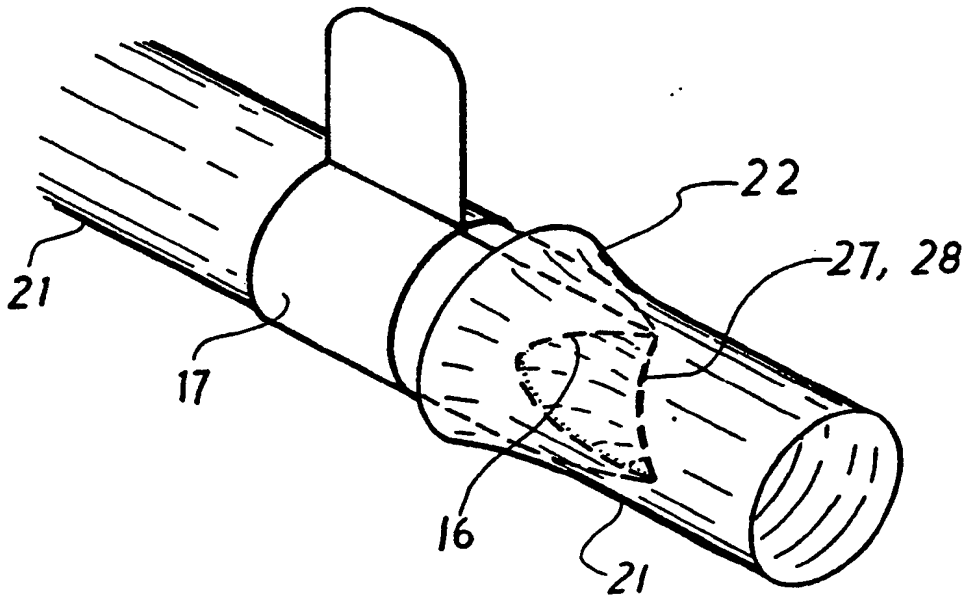

FIG. 5

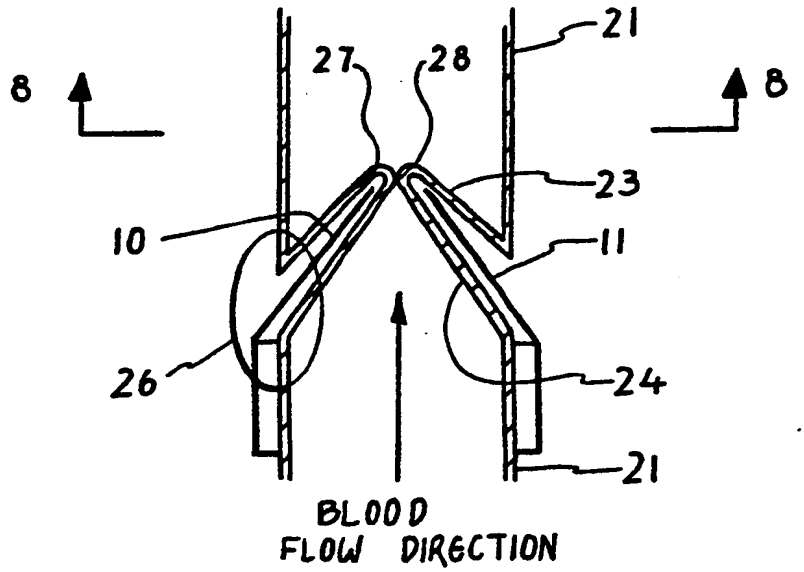

FIG. 7

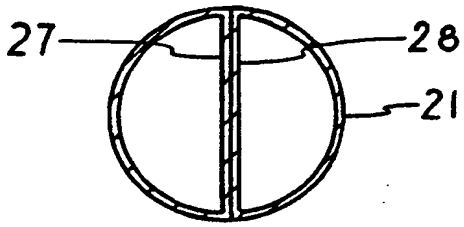

FIG. 8

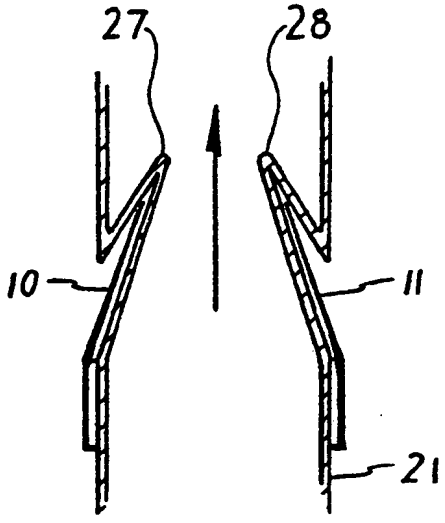

FIG. 9

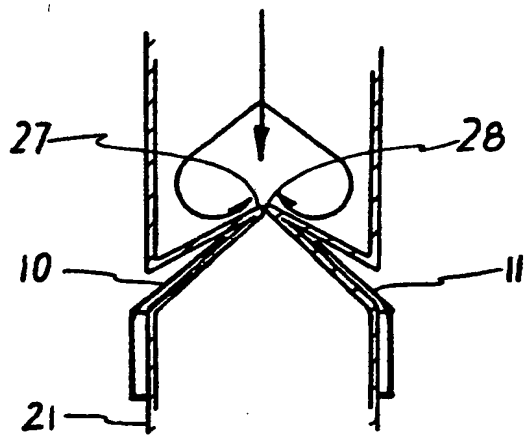

FIG. 10

INTERNATIONAL SEARCH REPORT

International Application No PCT/AU87/00220

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)

According to International Patent Classification (IPC) or to both National Classification and IPC

Int. Cl.[4] A61F 2/04, 2/02

II FIELDS SEARCHED

Minimum Documentation Searched

Classification System	Classification Symbols
IPC	A61F 1/00, 1/24, 2/02, 2/04, 2/06
US Cl.	623/1, 623/12

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched

AU : IPC as above

III DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
A	US,A, 4350492 (WRIGHT et al) 21 September 1982 (21.09.82)	
A	US,A, 3926175 (ALLEN et al) 16 December 1975 (16.12.75)	
A	GB,A, 1354691 (BLACK et al) 30 May 1974 (30.05.74)	
A	DE,A, 2733150 (HEIDBRINK) 1 February 1979 (01.02.79)	

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IV CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
7 October 1987 (07.10.87)	(13.10.87) 13 OCTOBER 1987
International Searching Authority: Australian Patent Office	Signature of Authorized Officer: H.W. Ness — H.W. NESS

Form PCT/ISA/210 (second sheet) (January 1985)

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON
INTERNATIONAL APPLICATION NO. PCT/AU 87/00220

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report	Patent Family Members		
US 4350492	AU 87504/82	BR 8204925	CA 1226403
	EP 73624	ES 515182	ES 522460
	ES 522461	JP 58041552	ZA 8206122

END OF ANNEX